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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,828	12/27/2006	Kenneth Walsh	701586-54555	3689

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,828	WALSH ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4-23-08&8-1-08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 21-24* is/are pending in the application.

4a) Of the above claim(s) *3,7,9-11,13-16 and 21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,8,12 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-6-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 17-20 have been canceled. Claims 1-16 and 21-24 are pending.

Applicant's election of Group II, claims 1-6, 8-10, 12 and 21-24, and the species of cardiac hypertrophy in the reply filed on 4-23-08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The response filed 8-1-08 is noted, which fixed problems with the claim set.

In the response filed 4-23-08, applicants state claims 7, 11, 13-16 are withdrawn as being non-elected groups and species. However, claims 3, 9, 10 and 21-23 do not read on cardiac hypertrophy. Claims 3 and 9 require the disease is associated with insufficient angiogenesis, which does not correlate to cardiac hypertrophy. Claim 10 requires cardiac myopathy which is not the same as cardiac hypertrophy. Claims 21-23 require various cardiac diseases none of which are cardiac hypertrophy. Accordingly, claims 3, 7, 9-11, 13-16 and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 2, 4-6, 8, 12 and 24 are under consideration in the instant office action.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4-6, 8, 12 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a mammal having a

disruption in an adiponectin gene and having cardiac hypertrophy comprising injecting a vector encoding adiponectin operably linked to a promoter intrajugularly to said mammal such that cardiac hypertrophy is treated, does not reasonably provide enablement for treating any cardiac hypertrophy, using any means of administration or using an inducible promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

Claim 1 is drawn to stimulating angiogenesis in a tissue by administering a nucleic acid sequence encoding adiponectin or angiogenic stimulating portion thereof operably linked to a promoter. The claim encompasses treating any tissue of any species. However, the specification is limited to treating mammalian tissue in vivo. Therefore, the claims should be limited to treating mammals in vivo and injecting the nucleic acid sequence into mammals.

Claim 24 encompasses treating any mammal having cardiac hypertrophy. Cardiac hypertrophy is defined as “enlargement of myocardial cells and hyperplasia of nonmuscular cardiac components due to pressure and volume overload and sometimes to neurohumoral factors" (Dorland’s Medical dictionary definition of “cardiac hypertrophy,” 2008). However, the specification and teachings in the art are limited to providing a nucleic acid sequence encoding adiponectin to adiponectin knockout mice having cardiac hypertrophy (pg 34 of the instant specification; Shibata, Nature Med., Dec. 2004, Vol. 10, No. 12, pg 1384-1389). The specification does not correlate adiponectin knockout mice having cardiac hypertrophy to any other mammal having

cardiac hypertrophy. While restoring adiponectin in patients with a disruption in the adiponectin gene may restore a number of disease-related phenotypes, it is not clear that adiponectin treats any type of cardiac hypertrophy as claimed. If applicants have evidence that adiponectin treats cardiac hypertrophy in those without a disruption in an adiponectin gene, please provide.

Claims 2 and 12 require using an inducible promoter. The specification and the art at the time of filing do not teach how or when to induce adiponectin expression under the control of an inducible promoter. Without such guidance, it would have required those of ordinary skill in the art undue experimentation to determine how or when to induce adiponectin expression under the control of an inducible promoter at the time of filing. Accordingly, the use of inducible promoters in conjuction with adiponectin gene therapy of cardiac hypertrophy is not enabled.

Claim 24 encompasses treating a mammal having cardiac hypertrophy by injecting a nucleic acid sequence encoding adiponectin by any means of delivery. However, the specification and teachings in the art are limited to providing a nucleic acid sequence encoding adiponectin to a mammal having cardiac hypertrophy via the jugular vein (pg 34 of the instant specification; Shibata, Nature Med., Dec. 2004, Vol. 10, No. 12, pg 1384-1389). The specification does not correlate intrajugular delivery of the vector to any other means of delivery such that cardiac tissue is targeted. Subcutaneous or tail vein injection would not target the damaged cardiac tissue. While some non-enabled embodiments are acceptable, claim 1 encompasses a whole host of

routes of injecting that would not target cardiac tissue. If applicants have evidence that other routes of gene therapy delivery treat cardiac hypertrophy, please provide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 8 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Zolotukhin (US Patent 6,967,018).

Zolotukhin injected adeno-associated virus encoding adiponectin into rats fed a high fat diet and diabetes intraportally (col. 13, lines 53-67). Without evidence to the contrary, the rats inherently had cardiac hypertrophy because they were diabetic and fat. Without evidence to the contrary, the cardiac hypertrophy was treated because Zoltukhin used a vector extremely similar to the one used by applicants that is clearly within the structure of the nucleic acid used in claim 1.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner